ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 11/06/07 for the Period Ending 11/06/07

Address	420 SAW MILL RIVER ROAD
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Telephone	914-347-4300
CIK	0001008848
Symbol	ACOR
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **November 6, 2007**

Acorda Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-50513**	**13-3831168**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

15 Skyline Drive, Hawthorne, NY	**10532**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(914) 347-4300**

Not Applicable
Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition

On November 6, 2007, Acorda Therapeutics, Inc. (the "registrant") issued a press release announcing its financial results for the quarter ended September 30, 2007. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item 2.02.

The information in this Item 2.02 of Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

99.1 Press Release dated November 6, 2007

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Acorda Therapeutics, Inc.

November 6, 2007

By: /s/ David Lawrence

Name: David Lawrence, M.B.A.
Title: Chief Financial Officer

Exhibit Index

Exhibit No	Description
99.1	Press Release dated November 6, 2007

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Third Quarter 2007 Financial Results

HAWTHORNE, NY, November 6, 2007—Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the third quarter 2007.

"We are very happy with the rapid enrollment in our second Phase 3 trial of Fampridine-SR, and look forward to reporting results from this trial in the second quarter of 2008, as well as results of our Thorough QT cardiac study in the first quarter," said Ron Cohen, M.D., President and CEO of Acorda Therapeutics. "In addition, we were pleased with the continued growth of our Zanaflex business. Based on our current projections, we expect our Zanaflex commercial operations to be cash flow neutral by the end of calendar 2007 and cash flow positive in 2008. This growth reflects the strength of our sales team, and positions us well for the anticipated launch of Fampridine-SR, if approved. We are also excited by the potential of our novel pipeline products as we move them toward IND stage."

Financial Results and Product Update
Zanaflex Gross Sales — For the quarter ended September 30, 2007, the Company reported gross sales of Zanaflex Capsules of $10.0 million and gross sales of Zanaflex tablets of $1.5 million providing combined gross sales of $11.5 million, compared to $5.0 million of Zanaflex Capsules and $1.5 million of Zanaflex tablets gross sales totaling $6.5 million combined gross sales for the same quarter in 2006. Included in the $1.5 million of gross tablet sales recorded in the third quarter of 2007 was $0.5 million of recognized revenue from 2 mg tablet deferred revenue. In August 2007, the right to return this product expired, allowing the Company to recognize the $0.5 million deferred revenue as gross sales.

Zanaflex Shipments — Zanaflex Capsules shipments for the quarter ended September 30, 2007 were $11.9 million and Zanaflex tablet shipments were $1.3 million providing total shipments of $13.2 million compared to $6.9 million of Zanaflex Capsules shipments and $1.8 million of tablet shipments for total shipments of $8.7 million for the same quarter in 2006.

Research and development expenses for the quarter ended September 30, 2007 were $5.6 million, including $0.3 million of share-based compensation, compared to $2.6 million, including $0.1 million of share-based compensation for the same quarter in 2006.

Sales, general and administrative expenses for the quarter ended September 30, 2007 were $11.6 million, including $1.6 million of share-based compensation, compared to $8.7 million, including $0.8 million of share-based compensation for the same quarter in 2006.

The Company reported a net loss of $8.5 million for the quarter ended September 30, 2007, or $.30 per diluted common share, compared to a net loss of $7.2 million or $.37 per diluted common share, for the same quarter in 2006.

As of September 30, 2007, the Company held cash, cash equivalents, and short-term investments of $105.1 million.

Fampridine-SR Clinical Update
As of November 2, the Company's Phase 3 study of Fampridine-SR, MS-F204, had 198 participants enrolled. Data from the study are expected in the second quarter of 2008.

The Company was invited to make both a platform and a poster presentation at the prestigious annual meeting of ECTRIMS, the European Committee on Treatment and Research in Multiple Sclerosis, which took place in Prague, Czech Republic, in October.

A Thorough QT cardiac study was initiated in September 2007 and data from that study are expected in the first quarter of 2008.

Preclinical Product Update
On October 9, researchers at Mayo Clinic presented details from a preclinical study showing that a recombinant human monoclonal antibody, being developed by Mayo Clinic and Acorda Therapeutics, administered in a single low dose in a laboratory mouse model of multiple sclerosis, can repair myelin, the insulating covering over nerve fibers in the central nervous system. Under a license agreement between Acorda and Mayo Clinic, Acorda holds exclusive worldwide rights to certain patents and other intellectual property for this antibody related to use and treatment of central nervous system disorders, including multiple sclerosis. Acorda and Mayo are collaborating to move this technology toward an Investigational New Drug application (IND) and clinical trials.

Corporate Update
On October 11, 2007, Acorda announced that it filed a lawsuit against Apotex Corp. and Apotex Inc. asserting infringement of the Company's U.S. Patent No. 6,455,557 relating to multiparticulate tizanidine compositions, such as those sold by the Company as Zanaflex Capsules ™ (tizanidine hydrochloride). The patent expires in 2021. The lawsuit is in response to Apotex Inc.'s Paragraph IV Certification Notice to the Company advising that Apotex Inc. had submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) seeking marketing approval for generic versions of the Company's three Zanaflex Capsules dosage strengths.

Webcast and Conference Call
Ron Cohen, M.D., President and Chief Executive Officer and David Lawrence, Chief Financial Officer, will host a webcast and conference call today at 8:30 am ET to review the Company's third quarter 2007 results.

The live webcast and accompanying slides may be accessed on Acorda's website at http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=1668450. To access the call only, please dial 866-203-2528 (domestic) or 617-213-8847 (international) and provide the access code 20548970 five minutes prior to the start time.

An archived webcast of the call can also be accessed from the Company's website, at http://www.acorda.com, for the next 30 days. A replay of the call will be available for 30 days from 10:30 a.m. Eastern Time on November 7, 2007 until 11:59 p.m. Eastern Time on December 7, 2007. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and provide the access code 47508787.

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company developing therapies for spinal cord injury, multiple sclerosis and related nervous system disorders. The Company's marketed products include Zanaflex Capsules™ (tizanidine hydrochloride), a short-acting drug for the management of spasticity. Acorda's lead clinical product, Fampridine-SR, is in a Phase 3 clinical trial to evaluate its safety and efficacy in

improving walking ability in people with MS. The Company's pipeline includes a number of products in development for the treatment, regeneration and repair of the spinal cord and brain.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or prospects should be considered forward-looking. These statements are subject to risks and uncertainties that could cause actual results to differ materially, including Acorda Therapeutics' ability to successfully market and sell Zanaflex Capsules, the risk of unfavorable results from future studies of Fampridine-SR, delays in obtaining or failure to obtain FDA approval of Fampridine-SR, competition, failure to protect its intellectual property or to defend against the intellectual property claims of others, the ability to obtain additional financing to support Acorda Therapeutics' operations, and unfavorable results from its preclinical programs. These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities and Exchange Commission. Acorda Therapeutics may not actually achieve the goals or plans described in its forward-looking statements, and investors should not place undue reliance on these statements. Acorda Therapeutics disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

Acorda Therapeutics, Inc
Condensed Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	September 30, 2007	December 31, 2006
Assets		
Cash, cash equivalents and short-term investments	$ 105,134	$ 53,756
Trade and grant receivable, net	3,806	4,389
Other current assets	3,985	7,867
Finished goods inventory	7,178	6,221
Property and equipment, net	1,741	1,223
Intangible assets, net	14,333	10,178
Other assets	681	734
Total assets	$ 136,858	$ 84,368
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 14,049	$ 14,033
Deferred product revenue	19,572	20,441
Current liabilities	3,037	4,436
Long term notes payable	6,654	6,695
Non-current portion of revenue interest liability	18,527	20,094
Stockholders' equity	75,019	18,669
Total liabilities and stockholders' equity	$ 136,858	$ 84,368

Acorda Therapeutics, Inc
Consolidated Statements of Operations
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30	
	2007	2006	2007	2006
Gross sales - Zanaflex	$ 11,507	$ 6,538	$ 30,810	$ 18,304
Less: discounts and allowances	(1,068)	(381)	(2,576)	955
Net sales	10,439	6,157	28,234	19,259
Grant revenue	20	70	36	371
Total net revenue	10,459	6,227	28,271	19,630
Cost of sales	(2,182)	(1,652)	(5,746)	(4,037)
Gross profit	8,278	4,575	22,524	15,593
Operating expenses:				
Research and development	5,603	2,595	12,854	8,892
Sales and marketing	7,918	5,297	22,006	14,142
General and administrative	3,720	3,435	12,550	9,273
Total operating expenses	17,241	11,327	47,410	32,307
Operating loss	$ (8,963)	$ (6,752)	$ (24,886)	$ (16,714)
Other income (expense), net	431	(418)	641	(750)
Cumulative effect of change in accounting principle	—	—	—	454
Net loss	(8,532)	(7,170)	(24,245)	(17,010)
Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders	—	—	—	(36,007)
Net loss	$ (8,532)	$ (7,170)	$ (24,245)	$ (53,017)
Net loss per common share - basic and diluted	$ (0.30)	$ (0.37)	$ (0.95)	$ (3.17)
Weighted average per common share - basic and diluted	28,209	19,633	25,468	16,746